Inspection Type

*Category:

795 Inspection

Facility Information

*Name:

DEA #:

Phone #:

e.g., 123-456-7890

*Permit Type:

*Permit Class:

*Permit #:

Inspection Type:

Inspection Date:

*Address 1:

Supervising Pharmacist:

Address 2:

Supervising Pharmacist License Number:

*City:

*State:

*Zip:

Compounding Manager / Designated Person:

*County:

Compounding Manager / Designated Person License Number:

*Type of Practice:

Types of Compounds

The pharmacy compounds the following medications:

*Solid oral preparations:

*Liquid oral preparations:

*Topical Preparations (creams, gels, and ointments):

*Optic preparations:

*Nasal and sinus preparations intended for local application (nasal sprays and nasal irrigation):

*Rectal preparations

*Vaginal preparations:

Inspection Questions

✓ Y	✗ N	! NA	! NI	Inspection Item	Comments
Set Section N/A				**Pharmacy Operations**	
1)				Does the pharmacy dispense compounded preparations pursuant to a prescription/order?	
2)				Does the pharmacy compound an approved commercially available product? - The compounded preparation produces a clinical difference from a commercially available drug that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner.	
3)				Does the pharmacy perform compounding with hazardous APIs or antineoplastic drugs requiring manipulation?	

4)		Does the pharmacy perform central prescription filling	
5)		Pharmacy has Policy/Procedure manual to outline and explain all components and operations of compounding non- sterile products.	
6)		Is the pharmacy licensed in other states?	
7)		Does the pharmacy hold any accreditations?	
8)		Has the pharmacy been inspected by any other agencies or organizations?	
9)		Is the pharmacy under any restrictions, limitations or waivers by any state the pharmacy is licensed in?	
10)		All pharmacists and technicians hold an active registration with the Kentucky Board of Pharmacy.	
Set Section N/A		**Personnel Training and Evaluation**	
11)		Personnel who compound or have direct oversight of compounding personnel, have demonstrated knowledge of principles and completed competency skills in at least the following. Must be completed initially and at least every 12 months after. • Hand Hygiene • Garbing • Cleaning and sanitizing • Handling and transporting components and CNSPs • Measuring and mixing • Proper use of equipment and devices selected to compound CNSPs • Documentation of the compounding process	
12)		The pharmacy has a training program to equip personnel with knowledge and training in the required skill necessary to perform their assigned tasks.	

Set Section N/A

13)		Personnel engaged in compounding maintain appropriate hand hygiene and maintain appropriate cleanliness required for the type of compounding performed. (USP 795 - (3.1)	

Set Section N/A

Personal Hygiene and Garbing

14)		Before entering the compounding area, personnel remove any items that are not easily cleanable and that might interfere with garbing. (USP 795 - (3.1) • Remove personal outer garments • Remove all hand, wrist, and other exposed jewelry • Remove earbuds or headphones The designated person may permit accommodations as long as the quality of the CSP and environment will not be affected.	
15)		Personnel perform the appropriate hand hygiene procedures before entering the compounding area. (USP 795 - (3.2) • Wash hand with soap and water for at least 30 seconds • Dry hands completely with disposable towels or wipers • Don gloves	
16)		Gloves are worn for all compounding activities. (USP 795 - (3.3) • Wash hand with soap and water for at least 30 seconds • Dry hands completely with disposable towels or wipers • Don gloves	
17)		Garb (e.g., Shoe covers, hair covers, facial hair covers, face masks, and gowns) are appropriate for the type of compounding performed and as needed for the protection of personnel from chemical exposure and for prevention of CNSP contamination. (USP 795 - (3.3) • If gowns are reused, they remain in the compounding area	

Set Section N/A	**Facilities**	
18)	The pharmacy has a designated area for nonsterile compounding with cleanable surfaces to include walls, ceilings, and floors (34-23-152) • Maintained in a clean orderly, sanitary condition and in good state of repair (USP 795 - (4.1) • Provides orderly placement of equipment and materials to prevent mix-ups among components, containers, labels, and finished CNSPs • Arranged and used in a way that minimizes cross contamination from non-compounding areas	
19)	The temperature of the drug storage area is monitored daily. (USP 795 - (4.2) • Readings are documented at least daily or stored on continuous reading device. • Monitoring devices must be verified for accuracy every 12 months or as required by manufacturer.	
20)	Compounding area has an easily accessible sink with hot and cold water. (USP 795 - (4.3) • Located at least one meter away from the CVE or BSC. (USP 795 - (5.3) • Sink is emptied of all items unrelated to compounding. • Cleaned if visibly soiled before being used to clean any equipment used for non-sterile compounding.	

Set Section N/A	**Cleaning**	
21)	Cleaning and sanitizing the surfaces of the nonsterile compounding area occurs on a regular basis and a daily log is maintained. (USP 795 - (5)	

22)		Containment Ventilated Enclosure (CVE) or BSC horizontal surfaces are cleaned and sanitized between compounding CNSPs with different components. (USP 795 - (Table 2) • At the beginning of each shift, after spills, and when work surface contamination in suspected. • Monthly cleaning under the work surface of the BSC • Documented (USP 795 - (5)	
23)		Equipment used in compounding is cleaned and sanitized between compounding CNSPs with different components. (USP 795 - (6.1) • Cleaning is documented (USP 795 - (5)	
24)		Work surfaces are cleaned and sanitized between compounding CNSPs with different components. (USP 795 - (5) - (Table 1) • At the beginning of each shift, after spills, or when surface contamination is suspected.	
25)		Floors are cleaned and sanitized daily, after spills, and when surface contamination is suspected. (USP 795 - (Table 1)	
26)		Storage shelving is cleaned and sanitized every 3 months, after spills, and when surface contamination is suspected. (USP 795 - (Table 1)	
27)		Walls and ceilings are cleaned and sanitized when visibly soiled, after spills, and when surface contamination is suspected. (USP 795 - (Table 1)	

Set Section N/A

Equipment and Components

28)		The equipment and components used for compounding are suitable for the specific compounding process. (USP 795 - (6.1) • are not reactive, additive, or sorptive and do not alter the quality of the CNSP.	
29)		Equipment and devices are inspected prior to use and verified for accuracy as recommended by the manufacturer or at least every 12 months. (USP 795 - (6.1) • Daily calibration documented (USP 795 - (14)	

30)		The Containment Ventilated Enclosure (CVE) or Biological Safety Cabinet (BSC) is certified every 12 months. (USP 795 - (6.1)	
31)		Active Pharmaceutical Ingredients APIs: (USP 795 - (6.2.1) • Comply with the criteria in the USP-NF monograph, if one exists • Have a COA that includes specifications and test results for the component that show the API meets expected quality • From an FDA-registered facility	
32)		Purified water or sterile water for irrigation is used for compounding nonsterile drug preparations when formulations indicate the inclusion of water. (USP 795 - (6.2.1)	
33)		Upon receipt of components other than conventionally manufactured products, the COA is reviewed to ensure the component has met the acceptance criteria in a appropriate USP-NF monograph, if one exists, and the information is documented. (USP 795 - (6.2.2) • Receipt date • Quantity verified • Supplier name • Lot number • Expiration date • Results of any in-house or third party testing	
34)		Compounding personnel check that components used in compounding are of the correct identity, strength, purity, quality and have been stored under the required conditions before use. (USP 795 - (6.2.3) • Components, equipment, and containers are stored off the floor. (USP 795 - (4.2) • Any component found to be of unacceptable quality is labeled and segregated from active stock. (USP 795 - (6.2.2)	

Set Section N/A	**Master Formulation and Compounding Records**

35) A master formulation is created for each unique formulation of a CNSP and contains the following: (USP 795 - (7.1)

- Name, strength or activity, and dosage form of the CNSP
- Identities and amounts of all components, relevant characteristics of components (e.g., particle size, salt form, purity grade, solubility)
- Container closure system
- Complete instructions for preparing the CNSP including equipment, supplies, and description of compounding steps
- Physical description of the final CNSP
- Beyond use date and storage requirements
- Reference source to support the assigned BUD
- Calculations to determine and verify quantities and/or concentrations of components and strength or activity of the APIs
- labeling requirements
- Quality control procedures and expected results
- Other information needed to describe the compounding process and ensure repeatability

36)		A compounding record is created for each CNSP and contains to following: (USP 795 - (7.2) • Name, strength or activity, and dosage form of the CNSP • Date or date and time of the preparation of the CNSP • Assigned internal identification number • A method to identify the individuals involved in the compounding process • Name, vendor or manufacturer, lot number, and expiration date of each component • Weight or measurement of each component • Total quantity of the CNSP compounded • Assigned BUD and storage requirements • Calculations to determine and verify quantities and/or concentrations of components and strength or activity of the APIs • Physical description of the final CNSP • Results of quality control procedures • MFR reference for the CNSP	
Set Section N/A		**Release Inspections**	
37)		The compounding record is reviewed for accuracy and completeness by a pharmacist before the CNSP is released. (3423-70 -f-1) (680-x-2-.14) • The person and date of the final check is documented on the CR (USP - 795- (7.2)	
38)		The CNSP is visually inspected by a pharmacist to confirm that the CNSP and its labeling match the CR and the prescription or medication order. (USP 795 - (8.1)	
39)		The label of CNSP contains the following information. (USP 795-(9) • Assigned internal identification number • Active ingredients and their amounts, activity, or concentration • Storage conditions if other than controlled room temperature • BUD • Dosage form • Total amount or volume if it is not obvious from the container	
Set Section N/A		**Compounding Procedures**	

40)		Compounding was observed during the inspection.	
41)		Personnel have performed the proper hand hygiene and wear the appropriate garb for the type of compounding performed. (USP 795 - (3.3)	
42)		Equipment and work surfaces used during compounding are cleaned before compounding begins and between CNSPs with different components. (USP 795 - (6.1)	
43)		The weighing and mixing of APIs is conducted in a CVE or BSC.	
44)		A compounding record is completed and reviewed for accuracy by a pharmacist.	

Set Section N/A

Beyond Use Dates

45)		All CNSPs have a beyond use date in compliance with USP 795 BUD limits in the absence of a USP-NF compounded preparation monograph or CNSP specific stability information. (USP 795 - (Table 4) • A shorter BUD is assigned when the physical and chemical stability of the CNSP is less than USP 795 limits. • The BUD of the CNSP does not exceed the shortest remaining expiration date of any of the commercially available starting components • If the CNSP is prepared from one or more compounded components, the BUD does not exceed the shortest BUD of any of the individual compounded components	
46)		CNSPs with extended BUDs have stability information using a stability-indicating analytical method for the APIs. USP 795 - (10.5) • The BUD indicated by the study can not exceed 180 days.	

47)		Aqueous CNSPs with extended BUDs have passed antimicrobial effectiveness testing in accordance with <51> and have a container closure integrity test conducted. (USP 795 - (10.5) • Antimicrobial effectiveness testing is conducted once for each formulation in the particular container closure system in which it will be packaged. • antimicrobial effectiveness testing results from an FDA-registered facility or published in peer-reviewed literature sources if the formulation and container closure system are exactly the same. • Antimicrobial effectiveness testing may be performed on a low concentration and on a high concentration of the active ingredient	

Set Section N/A

Quality Assurance and Quality Control

48)		The pharmacy has a procedure for the recall of CNSPs. (USP 795 - (21.1) • Implementation and completion of the recall • Identify patients • Investigation • Corrective action	
49)		The pharmacy has a SOP for handling complaints such as quality, labeling, or possible adverse reactions. (USP 795 - (12.2) • Investigation into the cause of the problem • Corrective action • Documentation (nature, date received, response)	

Set Section N/A

Hazardous Drugs

50)		The pharmacy has policies and procedures for the following: • Receiving • Storage • Compounding • Cleaning • Spills	

51)		Antineoplastic HDs and all HD API's are unpacked in an area that is neutral/normal or negative pressure. (USP 800 - (5.1) - (10) • PPE, including chemotherapy gloves must be worn when unpacking HDs. • HDs are delivered to the storage area immediately after unpacking	
52)		Any HD API or antineoplastic HD's requiring manipulation and are stored separately from non-HDs. (USP 800 - (5.2) • Stored in an externally ventilated room • Negative pressure room with at least 12 air changes per hour	
53)		The pharmacy has a hazard communication program to ensure worker safety during all aspects of HD handling. (USP 800 - (8) • A written plan that describes how the standard will be implemented • All containers of hazardous chemicals must be labeled, tagged, or marked with the identity of the material and appropriate hazard warning. • Have an Safety Data Sheet (SDS) for each hazardous chemical they use and are readily accessible to personnel during each work shift. • Personnel who may be exposed to hazardous chemicals when working must be provided information and training before being able to work with hazardous chemicals • Personnel of reproductive capability must confirm in writing that they understand the risks of handling HDs	

54)		All personnel who handle HDs have received initial training and competency evaluations and at least every 12 months after on the following. (USP 800 - (9) • Overview of entity's list of HDs and their risks • Review of the entity's SOP's related to handling of HDs • Proper use of PPE • Proper use of equipment and devices • Response to known or suspected HD exposure • Spill management • Proper disposal of HDs and trace contamination	
55)		Hazardous CNSPs are compounded in a Containment Primary Engineering Control (C-PEC) such as a Containment Ventilated Enclosure (CVE) or Biological Safety Cabinet (BSC). (USP 800 - (5.3.1) • Externally vented or redundant HEPA filters in series	
56)		The CVE or BSC is certified initially and every 12 months. (USP 795 - (6.1)	
57)		The CVE or BSC is located in a room with the following: (USP - 800 (5.3.1) • Externally vented • At least 12 air changes per hour • Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas.	
58)		The surfaces of ceilings, walls, floor, fixtures, shelving, counters and cabinets where Hazardous CNSPs are compounded are smooth, impervious, free from cracks and crevices, and non-shedding. (USP 800 - (5.3.1)	

59) Compounding area has an easily accessible sink with hot and cold water. (USP 795 - (4.3)
- Located at least one meter away from the CVE or BSC. (USP 795 - (5.3)
- Sink is emptied of all items unrelated to compounding.
- Cleaned if visibly soiled before being used to clean any equipment used for non-sterile compounding.

60) Personnel who compound hazardous CNSPs are fully garbed with gowns, hair covers, shoe covers, 2 pair of chemotherapy gloves, and respiratory protection. (USP 800 - (7)
- Gowns are disposable and shown to resist permeability and close in the back. (USP 800 - (7.2)
- A second pair of shoe covers is donned before entering the HD compounding area. (USP 800 - (7.3)
- Appropriate eye and face protection is worn when there is a risk of spills or splashes. (USP 800 - (7.4)
- Gloves meet ASTM standard D6978 (USP 800 - (7.1)
- A NIOSH certified N95 mask or more protective respiratory is worn if there is a known or suspected airborne exposure to powders. (USP 800 - (7.5)

61) The following is doffed before entering areas where non-hazardous drugs are compounded. (USP 800 - (7.1) -(7.2) -(7.6)
- Outer pair of chemotherapy gloves before exiting the C-PEC
- Gown
- Outer shoe covers

62) The surfaces of the nonsterile compounding area are deactivated, decontaminated, cleaned and disinfected on a regular basis and a daily log is maintained. (USP 795-(5) (USP 800-(15)
- The appropriate PPE is worn. (gown, head, hair, shoe covers, respiratory protection, and two pair of chemotherapy gloves)

63)		Containment Ventilated Enclosure (CVE) or BSC horizontal surfaces are deactivated, decontaminated, cleaned, and disinfected between compounding CNSPs with different components. (Usp 795 - (Table 2) (USP 800 - (15) • At the beginning of each shift, after spills, and when work surface contamination in suspected. • Monthly cleaning under the work surface of the BSC • Documented (USP 795 - (5)	
64)		Equipment used in compounding is deactivated, decontaminated, cleaned and disinfected between compounding CNSPs with different components. (USP 795 - (6.1) (USP 800 - (15) • Documented (USP 795 - (5)	
65)		Work surfaces are deactivated, decontaminated, cleaned and disinfected between compounding CNSPs with different components. (USP 795 - (5) - (Table 1) (USP 800 - (15) • At the beginning of each shift, after spills, or when surface contamination is suspected.	
66)		Floors are deactivated, decontaminated, cleaned, and disinfected daily, after spills, and when surface contamination is suspected. (USP 795 - (Table 1) (USP 800 - (15)	
67)		Storage shelving is deactivated, decontaminated, cleaned and disinfected every 3 months, after spills, and when surface contamination is suspected. (USP 795 - Table 1) (USP 800 - 15)	
68)		Walls and ceilings are deactivated, decontaminated, cleaned and disinfected when visibly soiled, after spills, and when surface contamination is suspected. (USP 795 - (Table 1) (USP 800 - (15)	
69)		Personnel who perform deactivation, decontamination, cleaning, and disinfection are in compliance with USP 800 garbing requirements. (USP 800 - (15)	
70)		The pharmacy has a spill kit readily available in all areas where hazardous drugs are routinely handled. (USP 800 - (16)	

71)		An eyewash station and/or other emergency or safety precautions is readily available. (USP 800 - (5.3)	

Set Section N/A

Veterinary

72)		if compounded preparation (non-controlled) for verterinary use is not patient specific, then one of the following purposes must apply:(201 KAR 2:311) • emergency treatment; • Situations when a time delay would negatively affect a patient outcome; or • Diagnostic purposes;	
73)		Pharmacist shall receive a written, verbal, facsimile, or electronic requrest for a compound drug from a veterinary practioner that must indicate the formulation, strength and ordered quantity. (201 KAR 2:311)	
74)		A record of the request from a verterniary practioner for a compounded preparation shall be maintained pursuant to 201 KAR 2:071 and readily available for no less than 5 years. (201 KAR 2:076 Section 6(1) and (2)(a))	
75)		The compounded drug shall have a beyond use date. (201 KAR 2:311)	
76)		The veterinary institution or ambulatory unit shall maintain only an emergency stock supply. (201 KAR 2:311)	

77)		A label for not patient specific compound shall be generated for the compunded drug and shall include: (201 KAR 2:311) • The name of the requesting veterinarian; • The designated name of the strength of the componded drug; • The quantity dispensed; • If for a specific patient and the patient is a food producing animal, the withdrawal time; • A lot or batch number of the compounded drug; • The beyond use date for the compounded drug; • The date the compounded drug is dispensed; • The pharmacy's, name, address, and telephone; • Any special storage requirements; • A notation stating "For veterinary use"; and • Any auxiliary label required for the compounded drug	
78)		A non-controlled substance compounded drug is dispensed by a veterinarian for emergency take home use when in his or her professional judgment, failure to provide the drug would result in potential harm to the patient. (201 KAR 2:311)	
79)		If dispensed from the veterinary institution or ambulatory unit, a compunded drug prescription for a veterinary patient shall be for up to a 14-day supply in accordance with the veterinarian prescription and dispensing labeling requirementsd as established in 201 KAR 16:600. (201 KAR 2:311)	
80)		A compounded drug containing a controlled substance shall only be compounded for patient specific dispensing from the pharmacy to the ultimate user. (201 KAR 2:311)	

Additional Information

*** Inspector:**

*** Start of Inspection:**

mm/dd/yyyy --:-- --

*End of Inspection:

mm/dd/yyyy --:-- --

Type:

Follow Up:

Email Addresses to Receive Report:

*Email to Default Recipients:

Notes:

Person Providing Information

Full Name: